REMARKS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Upon entry of the above amendment, claim 1 will have been amended and claim 2 will have been canceled. Accordingly, claims 1, 3-7, and 10-17 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 1, 3-7, and 10-17 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

Claims 1, 2, 4-7, and 10-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over LIPKOVER (U.S. Patent No. 5,421,816) in view of SHIMADA et al. (U.S. Patent No. 5,267,985), KOST et al. (U.S. Patent No. 4,767,402), and HIDAKA et al. (U.S. Patent No. 4,990,340).

Although Applicants do not necessarily agree with the Examiner's rejection of claims 1, 7, and 14-17 on this ground, nevertheless, Applicants have amended independent claim 1 to clearly obviate the above noted ground of rejection in order to expedite prosecution of the present application. In this regard, Applicants note that LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. fail to teach or suggest the subject matter claimed in amended claim 1. Independent claim 1 has been amended to include the subject matter of dependent claim 2; and claim 2 has been canceled. In particular, claim 1, as amended, sets forth an ultrasonic percutaneous penetration device including, inter alia, an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit that controls irradiation conditions of the irradiation unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz; and wherein the active

ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract", and "wherein the control unit controls at least one of factors including the frequency, irradiation power, period between on and off of power and irradiation time, which are irradiation conditions of ultrasonic waves". Claim 7 sets forth an ultrasonic percutaneous penetration kit including, inter alia, a medicine containing an active ingredient; an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz; and wherein the active ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract". Claims 14-17 each set forth an ultrasonic percutaneous penetration method including, inter alia, contacting a skin surface with a medicine, and applying ultrasonic waves, providing an irradiation unit including a first transducer and a second ultrasonic transducer; and providing a control unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz; and wherein the active ingredient is at least one active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract".

The Examiner has asserted that the LIPKOVER patent discloses in column 5, lines 22-27, the control unit controlling the frequency, period between on and off of power and irradiation time. However, it is respectfully submitted that the Examiner has misinterpreted this section of the LIPKOVER patent. In this regard, LIPKOVER discloses, in column 5, lines 22-27, "the control electronics apply ultrasonic stimuli pulses to the skin by energizing the stimuli transducer

at a first frequency, preferably lying in the 5 KHz – 1 MHz range for a predetermined period of time (10-20 seconds)". Thus, LIPKOVER discloses that the electronics are controlled such that pulses are applied at a frequency for a predetermined period of time. In other words, the frequency and period of time are fixed in this instance. LIPKOVER does not teach or disclose that the frequency can be changed in value or in the amount of time applied. Thus, LIPKOVER does not disclose or teach that the controller *controls* the frequency, *controls* the period between on and off of power, *controls* irradiation time, or *controls* irradiation power.

Accordingly, the LIPKOVER patent fails to disclose or teach an ultrasonic percutaneous penetration device including, inter alia, "wherein the control unit controls at least one of factors including the frequency, irradiation power, period between on and off of power and irradiation time, which are irradiation conditions of ultrasonic waves", as set forth in amended claim 1.

Further, as recognized by the Examiner, the LIPKOVER patent fails to teach or suggest a second transducer that generates waves at a second frequency, and a control unit that controls first and second transducers, a frequency in the range of 3 MHz to 7 MHz, and an active ingredient selected from the group vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract.

The SHIMADA et al. patent teaches a drug delivery system including a second transducer and a voltage source that controls the transducers. However, the elements in combination (*i.e.*, a first transducer and a second transducer) do not merely perform the function that each element performs separately. Further, SHIMADA fails to teach or suggest a control unit as claimed in amended claim 1. Additionally, as recognized by the Examiner, SHIMADA et al. fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz. Thus, SHIMADA fails to cure the deficiencies of the

LIPKOVER device. Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a).

The KOST et al. patent is directed to ultrasound transdermal drug delivery that includes ultrasound having a frequency within a range of 0.2 MHz to 10 MHz. However, KOST et al. fails to teach or suggest a control unit "wherein the control unit controls at least one of factors including the frequency, irradiation power, period between on and off of power and irradiation time, which are irradiation conditions of ultrasonic waves" as claimed in amended claim 1.

Further, KOST et al. fails to teach or suggest controlling the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz. In this regard, Applicants note that KOST et al. teaches providing a frequency within a range of 0.2 MHz to 10 MHz.

The Examiner has contended that the range disclosed by KOST et al. encompasses Applicants' entire range, and that selecting a specific frequency would have been obvious to one having ordinary skill in the art, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

However, Applicants respectfully submit that Applicants' claimed frequency range is *not* the mere discovery of optimum or working ranges that involves only routine skill in the art, as asserted by the Examiner. On the contrary, Applicants' claimed frequency range provides improvements to the prior art that are both advantageous and unexpected. In this regard, Applicants' claimed invention provides that the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz. The ultrasonic wave frequency within the range of 3 to 7 MHz allows the medicine to effectively penetrate a target in a shallow

portion from the skin surface. See particularly page 10 of Applicants' specification. Accordingly, the ultrasonic frequency range of 3 to 7 MHz of Applicant's claimed invention provides distinct advantages over the prior art that are unexpected. Accordingly, it is respectfully submitted that, contrary to the Examiner's assertions, the claimed frequency range of 3 to 7 MHZ is *not* the mere discovery of a range involving only routine skill in the art.

Further, KOST et al. does *not* teach providing a *first* and a *second* transducer, nor providing a first and a second transducer and controlling the frequencies of *both* of the transducers so that the *frequencies* are within the range of 3 to 7 MHz.

Therefore, in view of all of the above, the KOST et al. patent fails to cure the deficiencies of the LIPKOVER device and method. Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a).

The HIDAKA et al. patent fails to teach or suggest providing ultrasonic waves to enhance the transdermal transfer of the glutathione; and also fails to teach or suggest selecting an active ingredient from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract. Moreover, HIDAKA et al. fails to teach or suggest selecting an active ingredient to obtain a desired effect of whitening, wrinkle reduction, slimming, or trichophytosis treatment. Clearly, then, HIDAKA et al. teaches neither the claimed active ingredient selected from the group consisting of vitamin C, vitamin C derivatives, kojic acid, glucoside, glutathione, kiwifruit extract, rose fruit extract, arbutin and acerola extract; nor the resulting advantages thereof, as in Applicants' invention. Therefore, the HIDAKA et al. patent fails to cure the deficiencies of the LIPKOVER device and method. Further, there is nothing in the cited prior art that would lead one of ordinary skill in the

art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a).

Therefore, as described in detail above, LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al., in combination, fail to teach or suggest the claimed combinations as set forth in amended claims 1, 7, and 14-17. Therefore, the SHIMADA et al., KOST et al., and HIDAKA et al. patents fail to cure the deficiencies of the LIPKOVER device and method, and even assuming, arguendo, that the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. have been properly combined, Applicants' claimed ultrasonic percutaneous penetration device, kit, and method would not have resulted from the combined teachings thereof.

Further, as described in detail above, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modifications suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al. Thus, the only reason to combine the teachings of LIPKOVER, SHIMADA et al., KOST et al., and HIDAKA et al. results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over LIPKOVER in view of SHIMADA et al., KOST et al., and HIDAKA et al. is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 3-6 and 10-13, which are at least patentable due to their dependency from claims 1 and 7 for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection, and an early indication of the allowance of claims 1, 3-7, and 10-17.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 1, 3-7, and 10-17. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Any amendments to the claims which have been made in this amendment, which do not narrow the scope of the claims, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered cosmetic in nature, and to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
Yuko MATSUMURA et al.

Bruce H. Bernstein
Reg. No. 29,027

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191